

On-pump Beating Heart Versus Arrested Heart Mitral Valve Replacement - Efficacy and Safety

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Received on 03.10.2018

Accepted on 16.16.2018

Abstract

Introduction: This study is aimed to determine the efficacy and safety of beating heart mitral valve replacement (MVR) surgery without aortic cross clamping (ACC) and continuous coronary perfusion under normothermia. **Methods:** This prospective study was conducted on the patients undergoing isolated MVR. In this study, 16 patients (Group A) underwent MVR using beating heart technique without ACC with continuous coronary perfusion and 16 patients underwent conventional MVR using ACC and cardioplegic arrested heart technique (Group B). The following variables were assessed: CPB time; total operative time; cardiac enzymes (CK-MB); intubation time; mediastinal drainage; blood transfusions; ionotropes use; re-explorations; cerebrovascular accidents (CVA); pulmonary complications; ICU stay days and peri-operative mortality. **Results:** Pre-operative data was equally matched in both the groups using propensity scoring. On analyzing intra-operative and post-operative it was found that CPB time ($p < 0.001$), total operation time ($p < 0.001$) ionotropic support ($p < 0.001$), ICU stay ($p = 0.04$) and CK-MB ($p < 0.001$) were found to be better in Group A with statistical significant difference ($p < 0.05$). The other post-operative parameters were found to be statistically non-significant. There was one mortality in both the group. **Conclusion:** Beating-heart MVR surgery is equally safe as conventional arrested MVR and provides for better myocardial protection and should be alternative method of MVR especially in poor myocardial reserve patients.

Keywords: Beating Heart; Mitral Valve Replacement; Myocardial Protection; Arrested Heart.

Introduction

It is well known and reported in various studies that during open cardiac surgery the leading causes of mortality and morbidity are deleterious side effects of prolonged cardio pulmonary bypass (CPB) and cardioplegic cardiac arrest resulting in post operative myocardial dysfunction [1,2]. Cardiac reperfusion injury is a well described phenomenon after ischemia following cardioplegic arrest [2].

Valvular operations are conducted on beating heart as the effective way to prevent re-perfusion

injury by avoiding cardioplegic arrest of heart. During beating heart MVR, the heart is kept empty and allowed to beat continuously while myocardial protection and blood supply is achieved by continuous coronary perfusion of heart. The interest in beating heart MVR as an alternative to cardioplegic cardiac arrest technique stems from increased familiarity with the off-pump technique for coronary bypass surgery grafting (CABG) surgery; an improved understanding of potential harms of cardioplegia (re-perfusion injury) and the development of improved myocardial perfusion techniques (antegrade coronary perfusion and retrograde coronary sinus perfusion).

This technique of beating heart has been observed to decrease the risk of uncontrolled myocardial ischemia, particularly in patients with borderline myocardial function and facilitates early myocardial improvement. Heart is under more physiologic conditions than cardioplegic arrested state with left ventricle beating continuously, have shown in various studies to result in better neuro-cognitive function, decreased ICU stay days, decreased intubation time, decreased inotropic dependence and most importantly decreased post myocardial injury CK-MB levels [1-4].

Methodology

This study was conducted from January 2015 to July 2015. Patients who were diagnosed with isolated mitral valve disease and planned

to undergo isolated mitral valve replacement surgery were included. Re-do MVR, MVR with other concomitant heart surgery, patient with ejection fraction <30% and acute iatrogenic mitral regurgitation were excluded from our study. A total of 48 patients were randomly selected and divided into two groups, i.e. group A (beating heart MVR) and Group B (cardioplegic arrest MVR). Demographics of patients were recorded and preoperative clinical parameters like atrial fibrillation; New York Heart Association (NYHA) class, congestive heart failure, and two dimensional echocardiography (2D Echo) findings were matched using regression propensity score. 16 pairs (32 patients) who had matching parameters on propensity scoring were selected. Both groups were comparable with mean standard deviation (SD) variables on 2D Echo as tabulated in Table 1 and Figure 1.

Table 1: Mean dimensions on 2D Echocardiography in both groups

Variable	Group A (n=16) (Beating heart MVR)	Group B (n=16) (Conventional arrested MVR)
Left Atrial Size (Cm.)	7.4 ± 2.1	7.2 ± 1.8
Left Ventricle Size (Cm.)	8.2 ± 1.8	8.4 ± 2.0
Left Ventricle Ejection Fraction (LVEF)(%)	48	46
Right Ventricle Systolic Pressure (RVSP) (mm Hg)	82	84
Associated Pulmonary Resistance (PR) (mm Hg)		
Very Severe	8	10
Severe	7	10
Associated Tricuspid Regurgitation (TR) (%)	4	6
Right Atrial (cm.)	6.8 ± 2	6.4 ± 1.6

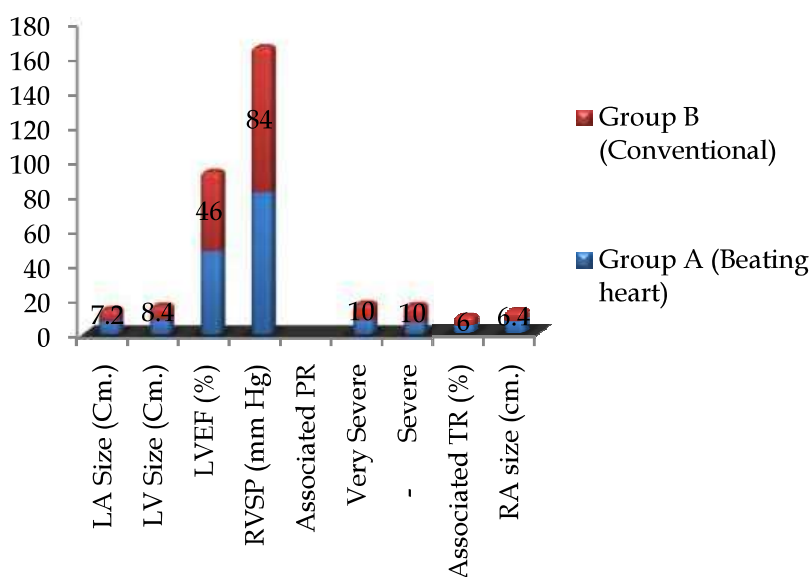


Fig. 1: Mean cardiac dimensions comparable in both groups

Table 2: Operative and Postoperative Data

Variable	Group A (n=16) (Beating heart MVR)	Group B(n=16) (Conventional Arrested MVR)	p-value
Total Operative time (Min.)	96±23	130±35	<0.001
CPB time (Min.)	57±11	80±14	<0.001
Length of ICU stay (Day)	0.9±0.2	1.8±0.3	0.04
Intubation time (Hrs.)	8±2.2	12±3.8	0.09
Mediastinal Drainage Vol. (ml)	475±56	550±80	0.78
Blood Tranfusion (Units)	1	2	0.06
Need of Inotrope (%)	20	55	<0.001
Re-exploration (%)	1	2.3	0.77
Major cerebrovascular event (%)	1.1	1.2	0.80
Pulmonary complication (%)	1.4	1.5	0.85
CK-MB (mean, SD) ng/ml	18±6	42±16	<0.001
Mortality	1	1	1.0

Operative and post-operative parameters were recorded for both group of patients. Operative parameters assessed were CPB time and total operative surgery time. Post-operatively numerous variables were recorded like serum cardiac enzymes (CK & CK-MB) at 4, 12 & 24 hours, ventilatory support time, mediastinal drainage indicating blood loss, blood transfusions, inotropic support, re-explorations, major cerebrovascular accidents (CVA); pulmonary complications, intensive care unit (ICU) stay days and mortality rates as depicted in (Table 2).

Surgical Technique

In both the group of patients standard CPB was established with aortic and bi-caval venous cannulation. Anticoagulation was achieved with heparin @300IU/kg-body weight. In all patients conventional sternotomy was done and MVR operation performed via classical left atriotomy. Carbon dioxide gas flooding of operating field was done to prevent air embolism. MVR was done using mechanical valve prosthesis in both group of patients. After valve implantation, retrograde (left atrial vent) as well as antegrade (aortic root vent) de-airing was meticulously done and patient gradually weaned off CPB. All patients underwent elective mechanical ventilation until they were ready for extubation after surgery in ICU.

In Group A, 16 patients underwent MVR using beating heart technique without cross clamping of aorta and coronaries were perfused through the normal coronary ostial naturally and continuously. The patient was operated under normothermic

condition (36°C-37°C). The mean systemic pressure was maintained above 70 mmHg and the maximum flow rate for CPB was calculated as per body surface area (2.4 litres/min/m²). The patients in this group were placed in Trendelenburg position during surgery to prevent air embolism.

In Group B, 16 patients underwent MVR using conventional antegrade cardioplegic arrest technique. Systemic temperature was lowered to 32°C. Local cooling done with ice slush. Tepid blood hyperkalemic cardioplegia was administered and was repeated every 20 min.

Statistical Analysis

The preoperative, operative & post operative variables were summarized using mean & standard deviation (SD) for continuous numeric variables. Analysis of variance (ANOVA) used to compare trends in rise & fall of CK-MB levels. Groups were compared using students t-test for numeric variables. Propensity score matching was performed to correct the effect of non-randomization of this study and selection bias. The significance of difference between the groups was expressed as p-value & p-value <0.05 was considered significant. Data were analyzed using SPSS software, version 18 (SPSS Inc, Chicago, IL).

Results

In our study, the patients had an age range from 20-50 years and included 60% females and 40% males. The demographic data and

pre-operative clinical parameters were equally matched and were not found to have statically significant difference. We had conducted this study from Januray 2015 till July 2015 and included 40 patients who had undergone isolated mitral valve replacement. These patients were divided in two groups - Group A (beating heart MVR) & Group B (conventional arrested heart MVR).

Post-operative analysis of the data is shown in Table -2. It was observed that there was statistically significant difference between CPB time ($p<0.001$) with favourable timings in Group A. Similarly, total operation time was more in group B ($p<0.001$) and ICU stay days less in group A (0.9 vs. 1.8; $p=0.04$).

The difference between the two groups remains non-significant in relation to intubation time (8hrs vs.12 hrs; $p=0.09$, Mediastinal Drainage Vol(ml) (475 ml vs. 550 ml; $p=0.78$), Blood Tranfusion volume (Units) (1 vs. 2; $p=0.06$) and re-exploration (%) ($p=0.77$).

There was no significant difference between incidence of major cerebro-vascular events as detected by computed tomography (1.1% vs 1.2%; $p=0.80$) and pulmonary complications (1.4% vs 1, 5%; $p=0.85$).

There was statistically significant difference in relation to inotropic requirement in post-operative period (20% vs 55%; $p<0.001$). Cardiac enzymes CK & CK-MB were measured at 4, 12 & 24 hours and the highest value was taken in consideration for statistical calculation. CK-MB values (ng/dl) was found to be significantly higher in group B patients (18 vs 42; $p<0.001$).

There were equal deaths in both the groups and was statistically non-significant.

Discussion

Advantages of beating heart mitral valve surgery are-

1. Well perfused myocardial muscle - least generation of free radicals.
2. Continuous perfusion, so no re-perfusion injury.
3. Heart that is regularly contracting / relaxing.
4. Technical possibility for ablation of atrial fibrillation on beating heart.
5. Testing of mitral valve repair done in real physiologic conditions in state of left ventricle beating tonus.
6. A more physiological natural heart.

For any cardiac surgery the myocardial preservation is of utmost importance. Two leading causes of morbidity in open cardiac surgery are the side effects of prolonged CPB and myocardial dysfunction caused by ischemia-reperfusion injury due to myocardial ischemia during cardioplegic arrest [1]. Myocardial arrest in diastole leads to myocardium edema which further causes myocardial dysfunction. The edema is induced by the lack of myocardial contractions and impaired lymphatic flow due to cardioplegia. In the beating heart, lymphatic drainage of the fluid within the interstitial space prevents the formation of edema [2]. However, reperfusion injury occurs invariably when aortic cross-clamp is removed in the arrested heart. During reperfusion, free oxygen radicals are released, which leads to myocardial damage. The beating heart provides better cardiac functioning by leading to a decrease in interstitial myocardial edema [3]. Normothermia decreases ill effects of hypothermia allowing normal coronary perfusion which is especially important in patients with impaired ventricular function. A beating heart MVR done under normothermia is helpful for patients with borderline myocardial function [1,4,5].

In our study we observed that patients operated via beating heart MVR in group A had significantly shorter CPB time (57 ± 11 min vs. 80 ± 14 min; $p<0.001$). Prolonged exposure to CPB has been known to have deleterious effects on patients undergoing open heart surgery as observed in many studies [6,7]. Thus, beating heart MVR with significantly lesser CPB time helps reduce post operative morbidity [8]. In our study, Group A patients had significant lesser operative time as compared to group B (96 min vs. 130 min; $p<0.001$). both these factors help in faster patient recovery in post -operative period.

Thompson et al. [9] in their study observed that patients undergoing beating heart MVR had lesser use of inotropic support and shorter hospital stay time. This was similarly noted by Miyairi T et al. [10] who found that less than 28% patients required inotropic support after beating heart MVR. In our study, we found statistically significant lesser use of inotropic support (20% vs 55%; $p<0.001$) and significant shorter ICU stay days (0.9 vs.1.8; $p=0.04$) in group A patients as compared to patients in group B. Shorter ICU stay days has been reported in beating heart MVR in other studies also [6-10].

In our study, some of the parameters in post-operative period were found to be better in patients undergoing beating heart MVR in group 1 than in patients of group 2; however these were not found to be significantly statistically than in

patients. In our study, the intubation time denoting ventilator time between the two groups was 8hrs vs. 12 hrs, ($p=0.09$). Mojena GC et al. [11] showed no statistically significant difference between the two study groups regarding the ventilation hours. However, Babaroglu S et al. [2] indicated a significant difference between the two groups concerning the post-operative ventilation period. Naseem A and colleagues [12] in their study found no significant difference between beating heart MVR and arrested heart MVR when compared for mediastinal drainage, blood units transfused, re-explorations and post-operative pulmonary complications. Likewise, we did not observe any significant difference between mediastinal drainage reflecting postoperative blood loss (475 ml vs. 550 ml; $p=0.78$), units of blood transfusion (1 vs. 2; $p=0.06$), percentage of patients requiring re-exploration (1 vs. 2.3; $p=0.77$) and post operative pulmonary complications (1.4% vs 1.5%; $p=0.85$). This insignificant difference in our study might be due to the small sample size.

Similarly, One of the major concerns for using beating heart MVR without aortic cross clamping is risk for cerebral air-embolism. We observed that in our our study major cerebro vascular injury was 1.1% in group A versus 1.2% in group B and was statistically non-significant ($p=0.08$). It is evident from the literature that major cerebrovascular events after open heart surgery varies between 1% and 4% [13,14]. Marco Ricci et al. [15] in a study of 59 patients operated on beating heart technique did not observe neurologic deficits in relation to air embolism, a potential concern when performing beating heart mitral valve surgery without clamping the aorta. Likewise in another study conducted by Thompson et al. [9] on 125 patients by utilizing the same approach, major cerebrovascular events were noted in two patients only 1.6%. These studies and our data support the fact that no major cardiovascular complications are associated with this technique [15,16,17].

Creatine kinase muscle brain (CK-MB) is a known specific marker for ischemic myocardial injury. We investigated CK-MB levels (ng/dl) in post operative period for patients of both group at 4, 12 and 24 hours and found levels of CK-MB to be significantly higher in group B (18 vs 42; $p<0.001$). Similar findings were reported by Babaroglua and colleagues [2] who studied both CK-MB levels and Troponin T levels in their study conducted on 319 patients and by Naseem et al. and other studies. [5,9,12,14]. Consistent with these results is the present finding of our study also that

maintenance of the heart in physiological beating state throughout the operation and eliminating the harmful effects of cardioplegia and hypothermia results in less myocardial damage than cardioplegic arrest.

There were one mortality in both the groups and the correlation to mortality was found to be statistically non-significant ($p=1.0$). Studies done by Babaroglua et al. [2] found that although mortality incidence were more in patients undergoing conventional arrested MVR, the relation was not statistically significant. Salerno TA and colleagues [18] found that mortality rates of beating heart MVR are comparable to arrested MVR. Similar, findings were observed by many other studies thus clearly defining that there is no added risk of mortality for patients undergoing beating heart MVR [12-14,19,20].

Although our study shows that there is definite advantage of operating MVR on beating heart continuous coronary perfusion at normothermia over conventional hypothermic hyperkalemic cardioplegic arrested heart, we feel that the study population size is small. Also, many preoperative patient parameters like diabetes mellitus, chronic obstructive pulmonary disease, ect were not well studied. This surgical technique of beating heart MVR needs to be done prospectively on bigger population size, with proper controlled randomization of both groups and in patients requiring complex surgeries like mitral valve repair procedures, multi-valve surgeries and MVR along with CABG surgeries.

Conclusion

Outcomes obtained from our study are found to compare favourably for the beating heart mitral valve replacement surgery versus conventional arrested MVR. The normal physiological beating heart recovers better in post-operative period and suffers lesser myocardial damage which maybe so very helpful for frail, borderline functioning hearts. A larger study will definitively cement beating heart MVR surgery technique in today's world cardiac surgery.

Source(s) of support in the form of grants, equipment, drugs, or all of these - NIL

Acknowledgement, if any

NIL

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